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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,069	02/15/2002	Roland Jurecic	39532-176599	8513

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VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER	
BERTOGLIO, VALARIE E	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,069	JURECIC ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5 and 11-25* is/are pending in the application.

4a) Of the above claim(s) *11-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment filed on 01/07/2004 has been entered. Claims 23-25 have been added. Claims 1,4,5 and 11-25 are pending and claims 1,4,5 23-25 and are under consideration in the instant action.

Election/Restrictions

Claims 11-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 9.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1,4,5 and 23-25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are directed an isolated nucleic acid that is at least 98% identical to SEQ ID NO:1, or a sequence complementary thereto, or a sequence that encodes a polypeptide identical to that encoded by SEQ ID NO:1. The specification has asserted that the nucleotide sequence set forth in SEQ ID NO: 1 encodes a hematopoietic precursor protein. The disclosed utilities for the nucleotide sequence set forth in SEQ ID NO:1 (as well as sequences complementary thereto and sequences that encode an identical polypeptide to that encoded by SEQ ID NO:1) include identification of tissues or cell types present in a biological tissue and diagnosis of diseases.

However, the specification fails to provide a specific and substantial utility for the claimed nucleotide sequences or the polypeptides that they encode. Neither the specification nor any art of record teaches what the polynucleotide of SEQ ID NO: 1 does or establishes a relationship of the polynucleotide of SEQ ID NO: 1 to any specific disease or establishes any involvement of the polynucleotide of SEQ ID NO: 1 in the etiology of any specific disease. While the specification has contemplated that the claimed sequences may be related to any of the diseases associated with aberrations at band 14q32 on human chromosome 14 (Table 1; page 16), no evidence has been presented that relates the claimed sequences to even one of these recited diseases. The specification teaches that the claimed nucleic acid maps to the same region as numerous hematological malignancies however it's function in hematopoietic cells is not demonstrated or characterized.

A substantial utility is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities under §101. Applicant's specification fails to provide a "real world" use of the nucleic acid set forth in SEQ ID NO: 1. Neither the specification as filed, nor any art of record disclose or suggest any biological or biochemical activity for the protein encoded by SEQ ID NO: 1 such that any utility would be well established for the nucleic acid. The asserted utilities for SEQ ID NO:1 such as identification of tissues or cell types present in a biological tissue and diagnosis of diseases are merely "potential" uses that apply to any uncharacterized, unrelated polynucleotide sequences. Therefore the asserted utilities are not considered "specific" utilities, i.e. they are not specific to SEQ ID NO:1.

The asserted utility of SEQ ID NO:1 is based on the assertion that SEQ ID NO:1 maps to the same region of chromosome 14 that is associated with a number of hematological malignancies. However, the specification has not provided any direct link between the claimed nucleic acid and any of these diseases or any other disease. The specification has not characterized the activity of the polypeptide encoded by the SEQ ID NO:1. Notably, the specification teaches that the polypeptide encoded by SEQ ID NO:1 has no known domains or motifs (page 13, paragraph 0053) and has not taught if the polypeptide has enzymatic activity, is a structural protein, a signaling protein or any other kind of protein. The specification and the art at the time of filing give no evidence relating to the role or activity of Hepp in cells or in causing a disease state. Given the teachings in the specification and the lack of teachings in the art, the only characteristic known about the protein encoded by SEQ ID NO:1 is that it is expressed in hematopoietic progenitor cells and maps to the same region as a number of different hematologic malignancies. Neither the specification nor any art of record has taught what type of activity is encoded by SEQ ID NO: 1 or what substrates it may act upon, whether it is a signaling molecule, a structural molecule or an enzyme, leaving the skilled artisan to speculate and investigate the uses of the uncharacterized gene product. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed nucleic acids. In view of the lack of guidance with respect to the type of polypeptide the claimed nucleic acids encode, the skilled artisan would not know how to use the claimed nucleotide sequence. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection of claims 1 and 4 is maintained for the reasons of record as set forth on pages 2-4 of the previous office action mailed 10/07/2003.

Applicants' arguments filed 01/07/2004 have been fully considered but are not found persuasive. Applicants assert that the number of sequences encompassed by the claims is finite and that the description provided in the specification is sufficient that the included subject matter would be known to one skilled in the art (see Applicants' response at page 5, paragraph 4). Applicant also argues that a nucleic acid 98% or 99% identical to SEQ ID NO:1 will have similar structure and function (page 6, lines 1-2).

In response, it is maintained that there is no evidence on the record of a relationship between the structure of any nucleic acid comprising a sequence at least 98% identical to SEQ ID NO:1 or a sequence that is complementary thereto, and the sequence set forth in SEQ ID NO:1 that would provide reliable information about the structure of any gene within the genus. There is no evidence on the record that the nucleic acids comprising a sequence at least 98% identical to SEQ ID NO:1 or a sequence that is complementary thereto, had a known structural relationship to SEQ ID NO:1. It is well known in the art that a single nucleotide change can alter

the function of a gene product. For example, Akaboshi et al has taught that a single point mutation at 25 different positions causes a loss of ALDH5A1 function, leading to disease (2003, Human Mutation, Vol. 22, pages 442-450, refer to Abstract and Figure 2). The specification fails to describe what 1% or 2% of the nucleic acid set forth by SEQ ID NO:1 can be changed without altering the structural or functional integrity of the protein normally encoded by SEQ ID NO:1 and therefore fails to meet the written description requirement for claims 1 and 4.

Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising SEQ ID NO:1 and a sequence that due to the degeneracy of the genetic code encodes a protein product identical to that of SEQ ID NO:1, does not reasonably provide enablement for any isolated nucleic acids that are less than 100% identical to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The previous enablement rejection is maintained for the reasons of record as set forth on pages 5-7 of the previous office action mailed 10/07/2003.

Applicants arguments filed 01/07/2004 have been fully considered and are not found persuasive. Applicants argue that the number of sequences encompassed by the claims are finite and can be made without undue experimentation. Applicant argues that such sequences would be expected by persons skilled in the art to have similar structure and function to SEQ ID NO:1.

In response, while substantial changes in NA sequence can be made while maintaining function as evidenced by the low level of sequence conservation of the SCCE gene between

species (see applicants' response, paragraph bridging pages 5-6) the specification fails to teach what nucleotide residues can be changed without affecting structure and function of the polypeptide encoded by SEQ ID NO:1. As set forth above, even single nucleotide changes can alter the structure and function of a gene product. A single nucleotide insertion or deletion can profoundly affect the structure of the encoded polypeptide. In light of the lack of guidance provided in the specification with respect to which nucleic acid residues within SEQ ID NO:1 can be changed, and how they can be changed, one of skill in the art would not know how to carry out the invention as broadly claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1,4,5 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Isomura (Genbank Accession AP000070, first published 04/08/1999). The rejection is maintained for reasons of record set forth on page 8 of the previous office action mailed 10/07/2003.

Applicants arguments filed 01/07/2004 have been fully considered and are not found persuasive. Applicant argues that the pending claims do not include fragments of SEQ ID NO:1 but only full-length sequences that are at least 98% identical to SEQ ID NO:1 and that the

claimed complimentary sequences are complementary to the entire sequence set forth by SEQ ID NO:1 (refer to applicant's response, page 7, 1st paragraph).

In response, the claims are drawn to "a sequence that is complementary", which can be interpreted as encompassing any sequence that is complementary to SEQ ID NO:1 including fragments of SEQ ID NO:1. As such, the art applies. However, the rejection may be overcome by amending the claim to limit it the nucleic acid to the sequence that is complementary over the entire length of SEQ ID NO:1.

Applicant also argues that the nucleic acid complementarity based on a stretch of 25 nucleotides and a score of 25 is meaningless in genetics. Applicant also argues that the region of complementarity with the nucleic acid set forth by Isomura is in a non-coding region of the Hepp cDNA and contains part of a polyadenylation signal in almost all of the 40,000 genes known or predicted to exist in the human genome (paragraph bridging pages 7-8). Applicant argues that the human and mouse Hepp genes are not conserved in the region highlighted by the art. Applicant also argues that Isomura's genomic DNA sequence originates from a different chromosome than the Hepp gene.

In response, these arguments are not persuasive and are irrelevant to the application of the prior art to the invention as broadly claimed. Again, the claims can be read to encompass any sequence that is complementary to a fragment of SEQ ID NO:1. Therefore, regardless of its functional relevance or significance, nucleotides 66558-66534 of Isomura teaches all of the limitations of the claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Fri 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PETER PARAS, JR.
PRIMARY EXAMINER

Pete Paras

Valarie Bertoglio
Examiner
Art Unit 1632